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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,465	04/13/2000	Robert F. Bencini	15916-261	7431

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Henricks Slavin & Holmes LLP
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EXAMINER

SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

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01/04/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/548,465	Applicant(s) BENCINI ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45,47,48,50-54,65,68-71,73-81,83-87,89,90,92-96 and 99-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45,71,75-79,95,96,101,104 and 105 is/are allowed.
- 6) ☒ Claim(s) 47,48,50-54,65,68-70,73,74,80,81,83-87,89,90,92-94,99,100,102,103 and 106-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/29/10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 47, 48, 50, 51, 53, 54, 80 and 81 is rejected under 35 U.S.C. 102(b) as being anticipated by Hammerslag et al. (US Patent No. 5,378,234). Hammerslag discloses an apparatus (Figs. 1-3 for example), comprising: an elongate body defining a diameter, a proximal portion and a distal portion and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (col. 5, line 55 through col. 6, line 5 and col. 6, lines 40-51 disclose that the device in Figs. 1-3 is provided with a wall); a stiffening member (26) associated with the distal portion of the elongate body and defining a proximal end, a distal end, a length that extends from the proximal end to the distal end, a proximal half that occupies one-half of the length and a distal half that occupies one-half of the length); an anti-tear device (28) positioned within the elongate body wall between the inner surface and the outer surface adjacent to at least a portion of the proximal half of the stiffening member (28 is positioned near the proximal end of 26) and not adjacent to

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the distal half of the stiffening member, and configured to prevent the stiffening member from tearing through the elongate body when the stiffening member bends (28 prevents at least the attached end of 26 from tearing through the body when it bends, wherein the body not only includes spring 14 but the inner and outer walls described above); and a steering wire (34) which is not connected to the anti-tear device and which is not located within the stiffening member, having a distal portion operably connected to the distal portion of the elongate body (34 is connected to 22/18); wherein the stiffening member and the distal portion of the steering wire are substantially diametrically opposed from one another (Figs. 1 and 3 disclose they are diametrically opposed). In reference to claims 48, 53, 54, 80 and 81 see Figs. 1-3 as well as Figs. 4-8. In reference to claims 50 and 51, the anti-tear device could also be interpreted as including member 14 which 28 is joined to. 14 is a tubular member along its length, and further comprises many slots. Please note that Applicant is not currently claiming structure which would prevent this interpretation.

Claims 52, 83-86, 106, 107, 108 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsuura et al. (US Patent No. 6,450,948). Matsuura discloses an apparatus (Figs. 1-22e for example), comprising: an elongate body defining a proximal portion and a distal portion (proximal portion near 50a/1150a in Figs. 4 and 22e and distal portion near 50b/1150b in Figs. 4 and 22e) and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an

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aperture in the distal portion (Figs. 1-5); a steering wire (56) having a distal portion operably connected to the distal portion of the elongate body (operably connected at 50b/1150b); a stiffening member (1150b/50b can be interpreted as the stiffening member as no other structure is claimed) associated with the distal portion of the elongate body; and a substantially c-shaped anti-tear device (Fig. 22e, c-shaped anti-tear device is 1154a/b with the longitudinal slot in it creating the c-shape), including first and second longitudinally extending edges that together define a slot (1167) which extends completely through the tubular member at the first and second edges, associated with the stiffening member (Fig. 22e discloses that 1150b is connected to the distal end of 1154a/b and therefore can be said to be associated with it) such that a portion of the stiffening member is distal of the anti-tear device (the examiner has defined the stiffening member as 1150b, which is located at the distal end of the device. The examiner has further defined the anti-tear device as 1154a/b, which is located proximally to 1150b. Therefore the stiffening member (1150b) is distal to the anti-tear device); wherein a portion of the steering wire is positioned within the slot (col. 8, lines 15-17). In reference to claims 83-86, 106 and 107, see Figs. 1-22e. In reference to claim 108, one could interpret the anti-tear device as being the first segment of 1154a/b which is directly adjacent to 1150b. This segment, as seen in Fig. 22e, is shorter than 1150b. Therefore if one interprets the anti-tear device in this manner, it can be said that the stiffening member (1150b) is longer than the anti-tear device.

Claims 68, 89 and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammerslag et al. (US Patent No. 5,378,234). Hammerslag discloses an apparatus (Figs. 1-3 for example), comprising: an elongate body defining a diameter, a proximal portion and a distal portion, the distal portion defining a longitudinal axis and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (col. 5, line 55 through col. 6, line 5 and col. 6, lines 40-51 disclose that the device in Figs. 1-3 is provided with a wall); a stiffening member (26), defining a proximal portion and a distal portion, associated with the distal portion of the elongate body such that the stiffening member will apply a force over an elongate body surface area when the stiffening member is bent (Fig. 3); anti-tear means (28 prevents at least the attached end of 26 from tearing through the body when it bends, wherein the body not only includes spring 14 but the inner and outer walls described above), secured directly to the proximal portion of the stiffening member and located within the elongate body wall between the inner surface and the outer surface, for increasing the elongate body surface area over which the force is applied when the stiffening member is bent to prevent the stiffening member from tearing through the elongate body (28 has a length and prevents at least the attached end of 26 from tearing through the body when it bends); and a steering wire (34), which is not connected to the anti-tear means, having a distal portion operably connected to the distal portion of the elongate body (34 is connected to 22/18); wherein the stiffening member and the distal portion of the steering wire are offset from one another by about

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180 degrees about the longitudinal axis (Figs. 1 and 3 disclose that 34 and 36 are diametrically opposed to each other). In reference to claims 89 and 90, see Figs. 1-8.

Claims 69, 73, 74, 92, 99 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebling et al. (US Patent No. 4934340). Ebling discloses an apparatus (Figs. 1-8 for example) comprising: an elongate body (Fig. 1) defining a longitudinal axis, a proximal portion and a distal portion and including a substantially solid single-piece wall (cross-sections of Figs. 2, 3 and 5-8 disclose that the wall is a single-piece wall) defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 7 discloses an embodiment in which lumen 186 ends in an aperture in the distal end); a steering wire (20) having a distal portion; an anchoring member (24) located within the distal portion of the substantially single-piece elongate body wall between the inner surface and the outer surface and secured to the steering wire (24 is attached to 20); a stiffening member (22) associated with the distal portion of the elongate body and defining a distal end, the distal end of the stiffening member being directly secured to the anchoring member; and a substantially tubular member directly secured to the stiffening member and defining a continuous length in a direction parallel to the longitudinal axis and a wall thickness (the examiner is interpreting the tubular member which is secured to the stiffening member to be the tubular body of the device, as Applicant has not claimed that the tubular member must be a separate component, and since 22 is embedded in the body, and

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the body is tubular, it meets the current claim language); wherein the steering wire is not connected to the substantially tubular member (Figs. 1-8 disclose that steering wire is connected to anchoring member 24 and that the steering wire slides within the body of the device to steer the device as the steering wire contracts within the device to pull the device in different directions and therefore there must be a degree of sliding of the steering wire which means it is not connected to the tubular body if it can slide within the tubular body). In reference to claims 73, 74, 92, 99, 102, see Figs. 1-9.

Claims 70, 93, 94, 100 and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebling et al. (US Patent No. 4934340). Ebling discloses an apparatus (Figs. 1-8 for example) comprising: an elongate body (Fig. 1) defining a longitudinal axis, a proximal portion and a distal portion and including a substantially solid single-piece wall (cross-sections of Figs. 2, 3 and 5-8 disclose that the wall is a single-piece wall) defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (Fig. 7 discloses an embodiment in which lumen 186 ends in an aperture in the distal end); a steering wire (20) having a distal portion; an anchoring member (24) located within the distal portion of the substantially single-piece elongate body wall between the inner surface and the outer surface and secured to the steering wire (24 is attached to 20); a stiffening member (22) associated with the distal portion of the elongate body and defining a distal end, the distal end of the stiffening member being directly secured to the anchoring member; and

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a substantially tubular member, including a slot through which the steering wire passes, directly secured to the stiffening member and defining a continuous length in a direction parallel to the longitudinal axis and a wall thickness (the examiner is interpreting the tubular member which is secured to the stiffening member to be the tubular body of the device, as Applicant has not claimed that the tubular member must be a separate component, and since 22 is embedded in the body, and the body is tubular, it meets the current claim language. The slot within the tubular member can be interpreted as the slot in which the steering wire is located and passes through. Since the steering wire is able to contract, it must be movable relative to the tubular device and therefore must be located within a slot). In reference to claims 93, 94, 100, 103 see Figs. 1-9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 65 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerslag et al. (US Patent No. 5,378,234) in view of Ebling et al. (US Patent No. 4934340) and in view of Samson (US Patent No. 5695483). Hammerslag discloses the device substantially as claimed including an apparatus (Figs. 1-3 for example), comprising: an elongate body defining a diameter, a proximal portion and a distal portion and including a wall defining an inner surface, an outer surface and a lumen extending from the proximal portion to an aperture in the distal portion (col. 5, line 55 through col. 6, line 5 and col. 6, lines 40-51 disclose that the device in Figs. 1-3 is provided with a wall); a steering wire (34) having a distal portion that is located within the elongate body wall between the inner surface and the outer surface and is operably connected to the distal portion of the elongate body (34 is connected to 22/18); a stiffening member (26) associated with the distal portion of the elongate body and defining a proximal end (near 28); and an anti-tear device (28 prevents at least the attached end of 26 from tearing through the body when it bends)), defining a proximal end and a distal end, secured directly to the proximal end of the stiffening member such that the proximal end of the anti-tear device is located within the distal portion of the elongate body wall between the inner surface and the outer surface; wherein the elongate body defines a distal end and at least a portion of the stiffening member is located proximal of the distal end of the elongate body (Figs. 1 and 3); and wherein the steering wire is not directly connected to the anti-tear device and is substantially diametrically opposed to the stiffening member (Figs. 1 and 3 disclose they are diametrically opposed). Hammerslag, however, does not disclose that the wall of the

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device is a solid wall formed from a single material. Ebling, however, discloses a similar catheter in which the cross sections of the catheter disclose that the catheter wall is made from a single solid material (catheter wall 10) and that the steering wire, stiffening member and the anti-tear device are embedded within the wall (elements 20, 22 and 24). Samson further discloses a catheter (Fig. 8) which has a solid wall with a spiral element embedded within it. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hammerslag's device by making the wall a solid wall from a single material, as taught by both Ebling and Samson, as Ebling teaches that it is was known in the art at the time of the invention to have a catheter with different steering wires and other structural elements embedded within a wall, which is also taught by Samson, and having a wall made from a single material enhances the stability of the device by eliminating joints where different materials are joined together which provides for a weaker device along the joints as they are stressed and strained and pulled apart during use of the device. In reference to claim 87, see Figs. 1-8.

Allowable Subject Matter

Claims 45, 71, 75-79, 95, 96, 101, 104, 105 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 45 and its dependent claims are allowed because the subject matter of the independent claim could either not be found or was not suggested in the

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prior art of record. The subject matter not found was the device comprising a tubular member that is a partial circle in cross-section and includes first and second longitudinally extending edges which define a slot, extending completely through the tubular member and a portion of the steering wire being positioned within the slot, in combination with the other elements of the claim.

Independent claim 71 its dependent claims are allowed because the subject matter of the independent claim could either not be found or was not suggested in the prior art of record. The subject matter not found was the anchoring member being located between the inner and outer wall surface and the substantially tubular member extending less than completely around the longitudinal axis and secured to the stiffening member, in combination with the other elements of the claim.

Response to Arguments

Applicant's arguments filed 10/29/2010 have been fully considered but they are not persuasive. In response to the arguments against the Matsuura reference regarding independent claim 52, it is the examiner's position, as stated in the modified rejection above, that Matsuura teaches that the stiffening member (1150b) is distal to the anti-tear device (1154a/b).

In response to the arguments against the Hammerslag reference regarding independent claims 47 and 68, it is the examiner's position that Hammerslag teaches an elongate body with an inner and outer wall (col. 5, line 55 through col. 6, line 5 and col. 6, lines 40-51 disclose using a lining on both the inner and outer surfaces of the device

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therefore creating a wall with an inner surface and an outer surface). Therefore it is the examiner's position that the anti-tear device (28) would help to prevent the stiffening member (26) from "tearing through the elongate body when the stiffening member bends". Since there are walls on either side of the coil member, it is possible that if not for the presence of the anti-tear device (28), the stiffening member's end could slip between the coils when the device is bent and tear through the walls of the elongate body. Therefore it is the examiner's position that Hammerslag teaches the device as is currently claimed. In response to Applicant's request for clarification of claims 50 and 51, please see the rejection above.

In response to the arguments against the Ebling reference regarding independent claims 69 and 70, it is the examiner's position that substantially tubular member is the tubular body of the device (10) and not ring 24 (which the examiner has defined as the anchoring member) as Applicant has stated. The examiner in the previous rejection and this rejection, has listed that the tubular member is the body of the device and the steering wire 20, slides within the tubular body and therefore is not connected to the tubular body.

In reference to independent claim 65, Applicant's arguments were persuasive, please see the new rejection above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764